

U.S. Navy commissioned the first American warship in honor of an African American, the USS *Jesse L. Brown*.

Hudner retired from the U.S. Navy at the rank of captain in 1973, and while his day-to-day service in the military would end, he continued to serve his fellow veterans through the USO and a variety of veterans' organizations. In fact, for most of the 1990s, Hudner served as commissioner of the Massachusetts Department of Veterans Affairs.

Today, the newly commissioned USS *Thomas Hudner* will serve as a living legacy to heroism and service. Think about it for a moment. When a sailor or Marine is assigned to this ship, they will proudly tell their family and friends about Hudner and Brown. When the *Hudner* makes a port call, those in the communities it visits will see the ship in port and meet scores of crew members with "USS Thomas Hudner" stitched on their shoulder.

And when citizens around the world learn about Captain Hudner's specific act that the Navy has described as "conspicuous gallantry and intrepidity at the risk of his life above and beyond the call of duty," they will begin to understand what uncommon valor truly is. Tom Hudner's story will serve as an inspiration to a future generation of Americans.

Please allow me to thank Captain Hudner for his lifetime of exceptional service to our Nation and his dedication to his fellow veterans. I ask my colleagues and our Nation to join me in wishing him and his wife Georgia all the very best in the years ahead.

Mr. President, I yield the floor.

RECESS

The PRESIDING OFFICER. Under the previous order, the Senate stands in recess until 2:15 p.m.

Thereupon, the Senate, at 12:30 p.m., recessed until 2:15 p.m. and reassembled when called to order by the Presiding Officer (Mr. WEBB).

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT— MOTION TO PROCEED—Continued

Mr. REID. Mr. President, I ask unanimous consent that the Senate remain on the motion to proceed to S. 3187 until 4 p.m. today and that all other provisions under the previous order remain in effect at that time.

The PRESIDING OFFICER. Without objection, it is so ordered.

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. ALEXANDER. Mr. President, I thank the majority leader for bringing up this bill. He and the Republican leader have put on the floor a piece of legislation that affects nearly every American family. This will not have the fireworks some things we do have, because we have a lot of agreement on it, which is one reason it is on the floor. It has gone through the com-

mittee. Senator HARKIN and Senator ENZI have worked carefully with all of the Republicans, all of the Democrats on the committee, and many other people on a complex piece of legislation for a year, to bring to the floor the Food and Drug Administration Safety and Innovation Act—a bill that is likely to succeed.

We take our medicines for granted. During the Civil War, the Capitol was used as a hospital—this Capitol. Two thousand cots were set up in the House and Senate Chambers and the Rotunda. The first group of wounded arrived from the Second Battle of Bull Run and later from Antietam in September of 1862. Those soldiers did not have the benefit of antibiotics or other modern medicines that we take for granted today, and that contributed to a horrible number of deaths in the Civil War.

Still, as the 20th century dawned, disease cast a long shadow over the United States of America. A child born in 1900 could expect to live an average of 47 years. Infectious diseases took many children before they reached their teens. In 1900 pneumonia and influenza were the leading causes of death, followed by tuberculosis and diarrhea.

Physicians had few weapons to fight diseases. The medicines at the time included such things as mercury for syphilis and ringworm; digitalis and amyl nitrate for the heart; quinine for malaria; and plant-based purgatives. For most of human history, diabetes meant death, but insulin was introduced in 1923 commercially, and within a few years enough insulin was being produced to meet the needs of diabetes patients around the world.

It is hard to remember this, but vaccines began to be commercially produced only during the time of World War I. It was not until the time of World War II that we saw the introduction of widespread and effective antimicrobial therapies with the development and mass production of penicillin. Since then, the sky has seemed to be the limit.

Half of Americans take at least one prescription drug every day. One in six takes three or more. Many take over-the-counter medicines. It is a real miracle what has happened in terms of our lives with the introduction of medicines, and we rely upon the Food and Drug Administration to keep those medicines safe and effective, which is what this legislation is about.

I would like to renew my compliments to Senator HARKIN and Senator ENZI for bringing this bill to the floor in a condition where they have already worked out most of the issues. This bill is complex. It is long. It has 11 titles. It will help safe and effective drugs, medical devices, and biosimilar products get to the market and, more importantly, get them to the market more quickly so people who need help can use these medicines and devices.

We are reauthorizing two user fees. These things have absurd names. The

Prescription Drug User Fee Act is called PDUFA, and the Medical Device User Fee Modernization Act is called MDUFMA. There are two new ones, which are GDUFA and BSUFA. It is really absurd. I promise to never again use those phrases for these user fee programs. But they are critically important programs that give the Food and Drug Administration needed resources to review new medically necessary products.

For example, there is the Better Pharmaceuticals for Children Act. It is a part of what we are doing this week. I cosponsored it with Senators REED of Rhode Island, MURRAY, and ROBERTS. I thank them for the ability to work with them.

This makes permanent the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act. One is an incentive, and one requires pharmaceutical companies under certain circumstances, when they develop new drugs for adults, to figure out the effect that those drugs will have on children. Too often, we do not know the answer to that, and the drugs are either ineffective or can have bad results. It also reauthorizes the Pediatric Medical Device and Safety and Improvements Act to promote pediatric medical device development.

Another critical part of the bill has to do with the medical device approval process. The United States is a world leader in medical devices. In Tennessee we have lots of them, especially in Memphis. We need to improve the regulatory process. There are many who believe the FDA is over-regulating medical devices. That has a negative effect on the industry's ability to raise capital and create jobs. It does not make those devices any safer in the United States than they are in Europe. This will help address those problems. For example, it will allow customization of medical devices for small populations—that means five people or fewer—without going through a very burdensome approval process, and it changes the humanitarian device exemption to encourage and incent the development of devices to treat patients with rare diseases—that would be groups of patients of fewer than 4,000 people.

There is another problem that is addressed in this legislation. It is the generation of antibiotics dealing with antibiotic resistance. We know there is a growing problem with antibiotic resistance as bacteria continuously mutate and evolve in their resistance to the drugs and the medicines we develop. While efforts have been made to preserve existing antibiotics, drug development has not kept up with the pace. These changes will provide meaningful market incentives and reduce regulatory burdens.

In addition, I am very pleased with the results of our work in dealing with drug shortages. That is a part of this bill. It will give the FDA additional tools to help prevent drug shortages and require FDA to look internally at